

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

REGENERON PHARMACEUTICALS,
INC.,

Plaintiff,

v.

GENENTECH, INC.,

Defendant.

Civil Action No. 10-CV-08779

**REGENERON PHARMACEUTICALS, INC.'S MEMORANDUM OF LAW IN
SUPPORT OF ITS MOTION FOR LEAVE TO SUPPLEMENT THE COMPLAINT**

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I. INTRODUCTION

This action arises from a controversy created by Defendant Genentech, Inc. ("Genentech"). Genentech has indicated, among other things, that Regeneron Pharmaceuticals, Inc.'s ("Regeneron") VEGF Trap product will not have freedom to operate based on U.S. Patent Nos. 5,952,199; 6,100,071; 6,383,486; 6,897,294; and 7,771,721 (the "Genentech Davis-Smyth Patents"). *See* Complaint (D.I. 1) ¶¶ 2, 17. Regeneron disagrees with Genentech, and filed a complaint with this Court on November 19, 2010. Regeneron requests, among other things, a declaration that no activities relating to Regeneron's VEGF Trap infringe any valid claim of Genentech's Davis-Smyth Patents. *See* Complaint ¶¶ 1-2.

Genentech moved to dismiss the complaint for lack of subject matter jurisdiction. D.I. 8. Genentech argued that the dispute is not ripe because Regeneron had not yet submitted its Biologics License Application ("BLA") to the U.S. Food and Drug Administration ("FDA") at the time it filed the original complaint. *See* Genentech's Memorandum of Law in Support of Its Motion to Dismiss the Complaint for Lack of Subject Matter Jurisdiction ("Motion to Dismiss") (D.I. 9) at 11 ("There is no justiciable controversy here because Regeneron has not sought regulatory approval to commercialize VEGF Trap."). Regeneron, however, plead its intent to submit a BLA to the FDA before the end of the second quarter of 2011. Complaint ¶ 11. In addition, as Regeneron explained in its brief opposing Genentech's motion to dismiss, the relevant fact in analyzing declaratory judgment jurisdiction is not whether a BLA has already been submitted, but when FDA approval is reasonably expected. *See* Regeneron's Memorandum of Law in Opposition to Genentech's Motion to Dismiss the Complaint for Lack of Subject Matter Jurisdiction, filed Feb. 8, 2011, at 20-21. Genentech's motion to dismiss is currently pending.

Regeneron completed preparation of its BLA and submitted it to the FDA this past Friday, February 18, 2011. While BLA submission is not necessary for subject matter jurisdiction in this case, Regeneron nevertheless seeks to supplement its original complaint to allege the submission of the BLA to obviate argument over the issue. Regeneron also seeks to:

- add an allegation that Genentech declined to covenant not to sue Regeneron for patent infringement when Regeneron contacted Genentech shortly after filing the original complaint, a fact that courts have held evidences a live controversy; and
- add additional specificity regarding Genentech's statements that VEGF Trap does not have freedom to operate—in particular, Regeneron adds that such indications have come from Genentech's former CEO and current Chairman, Arthur Levinson.

Regeneron is taking these steps not because it believes there is any deficiency in its pleading of Genentech's affirmative acts, but because Genentech has taken the position that more specificity was called for.

Regeneron's proposed Supplemental Complaint is attached hereto as Exhibit A. A document showing the differences between the original Complaint and the proposed Supplemental Complaint is attached hereto as Exhibit B.

Because Regeneron did not know whether the Court would prefer the new facts plead as part of a supplemental pleading or as a new complaint, Regeneron took the precaution of filing a new complaint in the White Plains Division of the Southern District of New York (Civil Action No. 11-CV-01156). The new complaint contains the same allegations and facts as the proposed Supplemental Complaint. Regeneron will proceed in the way that the Court ultimately believes is most appropriate.

II. ARGUMENT

"[Federal Rule of Civil Procedure] 15(d) permits a party to move to serve a supplemental pleading and the district court may grant such a motion, in the exercise of its discretion, upon reasonable notice and upon such terms as may be just." *Quaratino v. Tiffany & Co.*, 71 F.3d 58, 66 (2d Cir. 1995).

"[L]eave to file a supplemental pleading should be freely permitted when the supplemental facts connect it to the original pleading." *Id.* (citations omitted). Courts allow supplementation where it "will promote the economic and speedy disposition of the controversy between the parties." *Judge v. New York City Police Dept.*, No. 05-2440, 2008 WL 5148737 at *2 (S.D.N.Y. Dec. 8, 2008) (internal quotation marks omitted).

"Absent undue delay, bad faith, dilatory tactics, undue prejudice to the party to be served with the proposed pleading, or futility, the motion should be freely granted." *Quaratino*, 71 F.3d at 66 (citing *Foman v. Davis*, 371 U.S. 178, 182 (1962)).

To the extent there exist any subject-matter-jurisdiction defects in a complaint, supplementation may be used to cure such defects. In *Prasco, LLC v. Medicis Pharmaceutical Corp.*, the Federal Circuit held that allegations in an amended complaint "regarding events that happened after the first complaint" can serve to establish declaratory judgment jurisdiction because "Rule 15(d) expressly allows for supplemental complaints to 'cure' defects in the initial complaint." 537 F.3d 1329, 1337 (Fed. Cir. 2008).

A. Regeneron Seeks To Supplement The Complaint With Facts Connected To The Original Pleading

Leave to supplement should be permitted here because Regeneron seeks to supplement the complaint with facts connected to the original pleading. First, Regeneron's pleading of last Friday's BLA submission is an update to its prior pleading of its intent to submit the BLA before the end of the second quarter of 2011. Second, Genentech's refusal to covenant not to sue

Regeneron when Regeneron contacted Genentech shortly after the filing of the original complaint is connected to Genentech's prior indications (which Regeneron disputes) that Regeneron's VEGF Trap will not have freedom to operate. Finally, Regeneron's pleading that such indications have come from Genentech's former CEO and current Chairman, Arthur Levinson, is simply additional specificity added to the original complaint at the request of Genentech.

B. Granting Leave To Supplement Will Promote The Speedy Disposition Of The Controversy Between The Parties

Leave to supplement will also promote the speedy disposition of the controversy. Should the court find any merit in Genentech's arguments for dismissal, the proposed Supplemental Complaint pleads facts—including the submission of Regeneron's BLA—that Genentech contends are necessary for subject matter jurisdiction. For example, Genentech wrote in its motion that "[t]here is no justiciable controversy here because Regeneron has not sought regulatory approval to commercialize VEGF Trap." Motion to Dismiss at 11. In fact, this statement was one of Genentech's two main argument headings. In its reply brief in support of its motion to dismiss, Genentech again emphasized its view that BLA submission is critical, repeating its mantra that "there is no justiciable controversy here because Regeneron has not sought regulatory approval to commercialize VEGF Trap" and arguing that "while Regeneron provides information about the steps it has purportedly taken to increase the likelihood that its BLA, if filed, will be granted quickly, the fact remains that *it is not on file*." Genentech's Reply Memorandum Of Law In Further Support Of Its Motion To Dismiss (D.I. 25) at 3 (emphasis in original).

Genentech also has taken issue with the specificity of Regeneron's pleading of the present adversity between the parties. Motion to Dismiss at 3-4. Regeneron does not agree with Genentech, but in light of the need to supplement the complaint to include the BLA submission,

it appears most efficient to simply add the information Genentech requests regarding the statements of its Chairman, instead of having a fight about the level of specificity required in pleading. Like the the original complaint, the proposed Supplemental Complaint pleads that Genentech's affirmative acts encompass statements from individuals in addition to Genentech's Chairman—in part because even after the original complaint was filed, statements have continued to be made that Regeneron's VEGF Trap does not have freedom to operate based on the Davis-Smyth Patents.

Finally, after filing of the complaint Genentech refused to grant a covenant not to sue, a fact the Federal Circuit has held confirmatory of adversity between the parties, and therefore an appropriate subject for supplementation. *Kos Pharms., Inc. v. Barr Labs., Inc.*, 242 F. Supp. 2d 311, 315 (S.D.N.Y. 2003) (citing defendant's "refusal to sign a covenant not to sue, as requested by [plaintiff]" as a factor indicating plaintiff's "reasonable apprehension of litigation").

Notably, Genentech does not dispute that it has refused to sign a covenant, or that case law makes this refusal a highly relevant factor in deciding whether a controversy between the parties exists. Instead, Genentech claims that its refusal cannot be considered by the Court, a position expressly rejected by the Federal Circuit in *Prasco*.

C. Regeneron Has Not Unduly Delayed Or Acted In Bad Faith

Regeneron has not delayed or acted in bad faith in seeking leave to supplement the complaint. Regeneron submitted its BLA this past Friday, February 18, 2011. Regeneron is filing this motion one court day following the BLA submission. Nor can Regeneron be accused of acting in bad faith. Regeneron plead in the original complaint that it intended to submit a BLA before the end of the second quarter of 2011, and Regeneron's BLA submission last Friday falls within that timeframe.

D. Supplementing The Complaint Will Not Prejudice Genentech And Is Not Futile

Genentech will not be prejudiced if the court grants leave to supplement. This case is in its earliest stage. Discovery has not yet commenced, and no trial date has been set. Genentech has moved to dismiss and has not yet answered the original complaint. The supplemental pleading relates to arguments that Genentech raised in its motion to dismiss for lack of subject matter jurisdiction. Genentech cannot now credibly claim any unfair disadvantage, at this pleading stage of the case, based on a supplemental pleading of facts that Genentech identified as important for adjudication of subject matter jurisdiction.

Regeneron also notes that supplementation is not futile. To the contrary, the submission of the BLA is the very act that Genentech identified (albeit erroneously) in its opening brief as necessary for subject matter jurisdiction. Motion to Dismiss at 4.

III. CONCLUSION

For the foregoing reasons, Regeneron respectfully requests entry of an order granting leave to supplement the complaint in the form attached hereto as Exhibit A.

Dated: February 22, 2011

Respectfully submitted,

By: /s/ Amir Naini

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